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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0968; FRL-9334-9]

Etoxazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of etoxazole in or on field corn and popcorn. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0968. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr.,

Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Autumn Metzger, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5314; e-mail address: *metzger.autumn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding

the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the harmonized guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0968 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of

your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0968, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 25, 2011 (76 FR 10584) (FRL-8863-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7783) by Valent USA Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.593 be amended by establishing tolerances for residues of the miticide/ovicide etoxazole, 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on corn, field, grain at 0.01 parts per million (ppm); corn, field, forage at 0.6 ppm; corn, field, stover at 2.5 ppm; corn, field, refined oil at 0.03 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 2.5 ppm; poultry, fat at

0.01 ppm; and poultry, liver at 0.02 ppm. That notice referenced a summary of the petition prepared by Valent, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being set and determined tolerances are not needed for poultry. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for etoxazole including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with etoxazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Etoxazole possesses low acute toxicity via all routes of exposure. It is not an eye or dermal irritant or a dermal sensitizer. No toxicity was seen at the limit dose in a 28-day dermal toxicity study in rats.

The liver is the main target organ in mice, rats and dogs. In a 90-day toxicity study in dogs, increased liver weights and centrilobular hepatocellular swelling in the liver were observed. Similar effects were observed in a chronic toxicity study in dogs at similar doses, indicating that systemic effects (mainly liver effects) occur at similar dose levels following short- through long-term exposure without increasing in severity. In a 90-day toxicity study in mice, hepatotoxicity (increased relative liver weight, liver enlargement, and centrilobular hepatocellular swelling) was observed at high doses. Similar effects were observed at the high dose in a mouse carcinogenicity study. Subchronic and chronic toxicity studies in rats produced similar effects (increased liver weights, centrilobular hepatocellular swelling, etc.) to those seen in mice and dogs. In addition, slight increases in thyroid weights and incisors were observed in subchronic and chronic toxicity studies in rats at high doses and at terminal stages of the study. Toxicity

was not observed at the highest dose tested (HDT) in another carcinogenicity study in mice. There is no evidence of immunotoxicity or neurotoxicity in any of the submitted studies.

Two studies in mice showed no evidence of carcinogenicity up to the HDT. In a rat carcinogenicity study, which was deemed unacceptable due to inadequate dosing, benign interstitial cell tumors (testis) and pancreas benign islet cell adenomas were observed (in females) at the high dose. These effects were not observed in an acceptable carcinogenicity study in rats at higher doses. In special mechanistic male rat studies there were no observable changes in serum hormone levels (estradiol, luteinizing hormone (LH), prolactin and testosterone) or reproductive effects (interstitial cell proliferation or spermatogenesis) noted. EPA classified etoxazole as "not likely to be carcinogenic to humans." Etoxazole is not mutagenic.

The toxicology data for etoxazole provides no indication of increased susceptibility, as compared to adults, of rat and rabbit fetuses to *in utero* exposure in developmental studies. The rabbit developmental toxicity study included maternal toxic effects (liver enlargement, decreased weight gain, and decreased food consumption) at the same dose as developmental effects (increased incidences of 27 presacral vertebrae and 27 presacral vertebrae with 13th ribs). In the 2-generation reproduction study conducted with rats, offspring toxicity was more severe (pup mortality) than parental toxicity (increased liver and adrenal weights) at the same dose, indicating increased qualitative susceptibility.

Specific information on the studies received and the nature of the adverse effects caused by etoxazole as well as the no-observed-adverse-effect-level (NOAEL) and the

lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document titled "Etoxazole. Human Health Risk Assessment for Proposed Uses in/on Field Corn and Pop Corn," pp. 24-27 in docket ID number EPA-HQ-OPP-2010-0968.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for etoxazole used for human risk assessment is discussed in Unit III.B., in the Table of the final rule published in the

Federal Register of April 13, 2011 (76 FR 20537) (FRL-8867-5) (*http://www.gpo.gov/fdsys/pkg/FR-2011-04-13/pdf/2011-8550.pdf.*)

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to etoxazole, EPA considered exposure under the petitioned-for tolerances as well as all existing etoxazole tolerances in 40 CFR 180.593. EPA assessed dietary exposures from etoxazole in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for etoxazole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Continuing Surveys for Food Intake by Individuals (CSFII). As to residue levels in food, an unrefined, chronic dietary exposure assessment was performed for the general U.S. population and various population subgroups using tolerance-level residues for all agricultural commodities and 100 percent crop treated (PCT) information.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that etoxazole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for etoxazole. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for etoxazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of etoxazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at h*ttp://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of etoxazole for chronic exposures for non-cancer assessments are estimated to be 4.761 parts per billion (ppb) for surface water and 0.746 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 4.761 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Etoxazole is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found etoxazole to share a common mechanism of toxicity with any other substances, and etoxazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that etoxazole does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The toxicology data for etoxazole provides no indication of increased susceptibility, as compared to adults, of rat and rabbit fetuses

to *in utero* exposure in developmental studies. In a rat reproduction study, offspring toxicity was more severe (pup mortality) than parental toxicity (increased liver and adrenal weights) at the same dose; thereby indicating increased qualitative susceptibility. Based on the concerns in this unit, a Degree of Concern Analysis was performed by EPA, which concluded that concern is low since:

i. The effects in pups are well-characterized with a clear NOAEL;

ii. The pup effects occur at the same dose as parental toxicity;

and

iii. The doses selected for various risk assessment scenarios are lower (~3000-fold lower) than the doses that caused offspring toxicity in the rat 2-generation reproduction study. Therefore, the endpoints selected for risk assessment are protective of the effects seen in the rat reproduction study.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for etoxazole is complete except for acute and subchronic neurotoxicity and immunotoxicity studies. Changes to 40 CFR 180.158 make acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200), and immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration. Although these studies are not yet available for etoxazole, the available data do not show any evidence of treatment-related effects on the immune system. Further, there is no evidence of neurotoxicity in any study in the toxicity database for etoxazole. Therefore, the EPA does not believe that conducting neurotoxicity and immunotoxicity studies will result in a

NOAEL lower than the NOAEL of 4.62 milligrams/kilograms/day (mg/kg/day) already established for etoxazole. Consequently, an additional database uncertainty factor does not need to be applied.

ii. There is no indication that etoxazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is qualitative evidence of increased susceptibility of offspring (pup mortality) compared to less severe parental effects (increased liver and adrenal weights) at the same dose in the rat multi-generation reproduction study, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs (10X for interspecies variation and 10X for intraspecies variation) to be used in the risk assessment. Therefore, there are no residual concerns regarding developmental effects in the young.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to etoxazole in drinking water. These assessments will not underestimate the exposure and risks posed by etoxazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term

risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, etoxazole is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to etoxazole from food and water will utilize 11 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for etoxazole.

3. *Short and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short- and/or intermediate-term adverse effect was identified; however, etoxazole is not registered for any use patterns that would result in short- and/or intermediate-term residential exposure. Short- and/or intermediate-term risk is assessed based on short- and/or intermediate term residential exposure plus chronic dietary exposure. Because there is no short- and/or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and/or intermediate-term risk), no further assessment of short- and/or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and/or intermediate-term risk for etoxazole**.**

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, etoxazole is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to etoxazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/nitrogen-phosphorus detection (GC/NPD) and gas chromatography/mass selective detection (GC/MSD) methods) are available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex

MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for etoxazole for the commodities discussed in this document.

C. Revisions to Petitioned-For Tolerances

Based upon analysis of the data supporting the petition using the Organization for Economic Cooperation and Development tolerance calculation procedures, the EPA revised the tolerance levels for corn, field, forage from 0.6 ppm to 0.80 ppm; corn, field, stover from 2.5 ppm, to 4.0 ppm and corn, pop, stover from 2.5 ppm to 4.0 ppm.

There is no reasonable expectation of finding quantifiable residues of etoxazole in poultry commodities based on the calculated maximum reasonable dietary burden (MRDB) for poultry (0.0077 ppm) and the results from the poultry metabolism study. Therefore, tolerances for residues of etoxazole in poultry, fat and poultry, liver were not required for this petition.

V. Conclusion

Therefore, tolerances are established for residues of etoxazole in or on corn, field, grain at 0.01 ppm; corn, field, forage at 0.80 ppm; corn, field, stover at 4.0 ppm; corn, field, refined oil at 0.03 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 4.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule

has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal*

Governments (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 13, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.593 is amended in paragraph (a) by alphabetically adding the following commodities to the table to read as follows:

§ 180.593 Etoxazole; tolerances for residues.

(a) *General*. * * *

Commodity	Parts per million
* * * * *	
Corn, field, forage	0.80
Corn, field, grain	0.01
Corn, field, refined oil	0.03
Corn, field, stover	4.0
Corn, pop, grain	0.01
Corn, pop, stover	4.0
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[FR Doc. 2012-1254 Filed 01/24/2012 at 8:45 am; Publication Date: 01/25/2012]